FINAL REPORT

For

DEVELOPING A CERTIFICATION PROTOCOL FOR ALTERNATIVE CLEANING CHEMISTRIES

A Joint Project Between

Lawrence Livermore National Laboratory
Pollution Prevention Group
and
California Environmental Protection Agency
Department of Toxic Substances Control
Office of Pollution Prevention and Technology Development

Disclaimer

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This document was prepared with guidance from the Alternative Cleaning System Stakeholder Panel, whose members are listed below. The panel was assembled expressly for this project, and their many suggestions were received with appreciation by the authors.

Alternative Cleaning Chemistries Stakeholder Panel

Panel Member	Credentials	Organization
Mike Beeks	Chemist and Cleaner Manufacturing	Brulin Corporation
Tom Barron	Engineer/P2 consultant	Thomas S. Barron, PE
Mike Callahan	Chemical Engineer	Jacobs Engineering Group - Environmental Services
Dr. Anupom Ganguli	Senior Manager, Stationary Source Compliance	South Coast Air Quality Management District
Louie Yuhas	Supervisor, Air Quality Analysis and Compliance	South Coast Air Quality Management District (alternate representative)
Dr. Cal Kodres	Mechanical/Environmental Engineer	Port Hueneme Naval Facilities Engineering Service Center
Kraig Kurucz	Chemical/Environmental Engineer	Lockheed/Martin Missiles & Space
Joe Lukas	Chemist and Cleaner Manufacturing	Inland Technology Incorporated
Zelco "Z" Halar	R&D Director	Inland Technology Incorporated (alternate representative)
Jim Miille	Chemist/P2 Consultant	Chemical Solutions Inc.
Dr. Jim Seward	Occupational Physician	LLNL Health Services
John Mukhar	Civil/Environmental Engineer	City of San Jose Environmental Services Department/San Jose-Santa Clara Water Pollution Control Plant
Ted Smith	Attorney	Silicon Valley Toxics Coalition
Dennis Zupan	Senior Chemist	Brulin Corporation

In addition to the panel members noted above, the following individuals contributed helpful comments, data, or other assistance to the authors. Their support is gratefully acknowledged.

Panel Guest	Credentials	Organization
Ron Block	President	Block Environmental Services
John Butenhoff	Manager, Toxicology Services	3M Specialty Chemicals
Corazon Choa	Principal Air Quality Chemist	South Coast Air Quality Management District
Victor Douglas	Air Resources Engineer	Air Resources Board
Rudy Eden	Laboratory Services Manager	South Coast Air Quality Management District
Alex Ekster	Associate Sanitation Engineer	City of San Jose Environmental Services Department/San Jose-Santa Clara Water Pollution Control Plant
Virginia Lew	Industrial Hygienist	LLNL
Mike Morris	Program Manager	Institute for Research & Technical Assistance
Karna Peters	Attorney, attending for 3M	Peters & Peters
Lael Pickett	Chemist	3M Specialty Chemicals
Kathleen Wolf	Executive Director	Institute for Research & Technical Assistance
Kurt Werner	Toxicology Specialist	3M Specialty Chemicals

Finally, the authors wish to express their gratitude for the guidance provided by Kim Wilhelm and Phil Loder of the California Department of Toxic Substances Control.

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Introduction

This Final Report summarizes the activities and results of the joint project between Lawrence Livermore National Laboratory (LLNL), the Alternative Cleaning Chemistries Stakeholder Panel, and the Department of Toxic Substances Control (DTSC), whose main focus was to develop detailed recommendations for a California-EPA Alternative Cleaning Chemistries Certification. The project also produced a set of preliminary ideas for an Alternative Cleaning Equipment Certification (for equipment or equipment/chemistry combined systems). This report attempts to capture the important points from the discussions held by the Stakeholder Panel and its guests regarding the different aspects of the criteria. These discussions will provide the reader with an idea of the range of different opinions that were considered in formulating the criteria. This report also examines issues peripheral to the criteria themselves, such as an approach to setting fees, and the appropriate composition of an Expert Panel[1] to evaluate Applicants' data and hear appeals.

This document includes the following sections

I. Developing the Criteria Recommendations: Roles of Project Participants and Recurrent Themes

II. Alternative Chemistries: Recommendations for Application and Evaluation Protocols

III. Discussion of the of the Alternative Cleaning Chemistry Recommendations
This section summarizes the major effort of the project. It includes the certification recommendations, as well as summaries of the divergent comments, opinions, and discussions about those recommendations.

IV. Preliminary Recommendations for Alternative Cleaning Equipment and Equipment/Chemistry Combination Systems

V. Certification Protocols

VI. Appeals Procedure Recommendations

VII. Periodic Review Requirements

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[1] The Expert Panel is defined as a group of specialists from various fields related to issues arising in industrial cleaning. The Panel will help evaluate applications and make decisions on appeals. (The Expert Panel is described in greater detail in Section II.)

Regulatory Basis and Intent of the Certification Program

Effective January 1, 1994, Chapter 412, Statutes of 1993, Section 25200.1.5, *Health and Safety Code* (enacted by California State Assembly Bill 2060, Weggeland) authorized the California-EPA's Department of Toxic Substances Control (DTSC) to certify the performances of hazardous waste environmental technologies. Such environmental technologies must meet both specific criteria noted below before being certified.

- They must be determined not to pose a significant potential hazard to the public health and safety or to the environment, when used under specified operating conditions.

- They can be operated without specialized training, and with minimal maintenance.

The purpose of the certification program is to provide a comprehensive, independent review of technologies to facilitate regulatory and end-user acceptance, and to promote and foster the growth of California's environmental technology industry. The certification program will identify cleaning chemistries and equipment whose use will help reduce health and environmental risks associated with industrial cleaning operations, without sacrificing cleaning performance.

Rationale for the Criteria

The need to replace many dangerous cleaning solvents with alternatives that pose less risk to human health and the environment has been clearly demonstrated by reputable studies and research. As a result, literally hundreds of alternative chemistries and cleaning equipment systems are now commercially available. While numerous environmentally safe and effective cleaning chemistries exist, others known to be associated with serious performance, environmental or health concerns are still widely employed. The alternative cleaning technology criteria are intended to provide a framework for industry and regulators to help evaluate the most useful of the technologies. The criteria should have the general support of the regulatory, manufacturing and research communities. Such criteria, applied to the evaluation of new cleaning technologies by state or local certification programs, will further the use of products that enhance environmental protection and quality, while promoting pollution prevention. For industrial shops redesigning their cleaning operations, the criteria will also serve as valuable guidelines in making the best engineering and product choices.

Manufacturer's Responsibilities

The manufacturer applying for certification will be responsible for the cost of certification, and must supply clear, accurate data on its product, as required by the certification protocol.

By accepting certification, the manufacturer will assume, for the duration of the certification, responsibility for maintaining the quality of the manufactured equipment and materials at a level equal to or better than was provided to obtain certification. The manufacturer will also agree to use the certification appropriately in its literature. Furthermore, the manufacturer will agree to allow quality monitoring by DTSC, as required by the statute under which a certification is granted.

I. Developing the Criteria Recommendations: Roles of Project Participants and Recurrent Themes

Role of LLNL, the Stakeholder Panel and Panel Guests

At the beginning of this project, DTSC and LLNL developed the initial issues that would serve as a basis for criteria development. They discussed the advantages of "make-or-break" criteria that could easily be applied to cleaning chemistries to produce "pass" or "no pass" results. More subjective criteria were also discussed, and they seemed to have a place in the certification criteria as well. Some of the initial questions explored issues such as:

- Shall a cleaning chemistry proven or suspected of being a human carcinogen, mutagen, teratogen, endocrine disrupter or neurotoxin be considered for certification?
- Shall a cleaning chemistry be considered if it is an ozone depleting compound?
- What volatile organic compound (VOC) concentration level should disqualify a cleaning chemistry from consideration?

As the project progressed, DTSC and LLNL jointly identified potential Stakeholder Panel members. It was vital to include specialists with a variety of related skill sets, individuals who would represent a whole spectrum of differing viewpoints. The personnel identified included representatives from cleaning chemistry manufacturers, industrial users (both large and small facilities), and California regulators (including personnel from the state and local levels). It is an indication of the importance of this project in these varied communities, that almost all of those approached to serve on the Panel agreed to do so, despite the considerable time away from their jobs and significant travel expenses.

All meetings were public, and attracted guests whose input was also valuable. In some cases, invited guests had particular areas of expertise useful to the discussions. For instance, a treatment specialist from the City of San Jose Environmental Services Department/San Jose-Santa Clara Water Pollution Control Plant (Alex Ekster) was invited to one meeting , and the owner/manager of an environmental testing laboratory (Ron Block) was invited to another.

The Panel convened for seven full-day meetings between October 1996 and November 1997, and reviewed criteria drafts and reference documents during interim times. The Panel's role was to generate concepts and ideas for a certification process that LLNL would then weave into criteria recommendations. The Panel reviewed and augmented these criteria drafts. DTSC remained close to the whole process in an oversight role.

Throughout the criteria development process, LLNL was responsible for facilitating Panel meetings, gathering background and reference material for Panel members, developing agendas, and writing criteria recommendation drafts that reflected the opinions of the Panel as accurately as possible. In addition, LLNL prepared the final criteria recommendations and this final project report for DTSC.

Relevant reference sources included:

- Manufacturers' data on alternative cleaning chemistries and cleaning equipment.
- Cleaning chemistry and cleaning equipment performance data.
- Methodologies for evaluating cleaning technology performance.
- Toxicity data.
- Methodologies for evaluating the health and environmental impacts of chemicals.

Recurrent Themes During Criteria Development

During the criteria development process, several topics inspired ongoing debate. While not recorded in any specific criteria recommendations, these pervasive themes helped shape the choices made by the Panel, and are summarized in the following sections.

Criteria Scope: Chemistries and Equipment

From early in the criteria development process, the Panel spent significant time on the scope of the criteria. A primary issue revisited many times concerned whether the criteria should be developed for cleaning systems (chemistries used in conjunction with delivery equipment) or whether one set of criteria should be developed for cleaning chemistries and a second for cleaning equipment.

The perceived benefits of the first alternative, certification of a cleaning system, suggested that a detailed set of criteria could be established to evaluate a specific cleaning chemistry used in conjunction with a specific type of delivery equipment. Some Panelists believed this approach was the most logical, and offered the best opportunity for a certification that would be protective of both human health and the environment. Under this paradigm, cleaning performance, equipment performance and chemical toxicity could be balanced.

The greatest perceived disadvantage to evaluating the chemistry/equipment combination was that the criteria and the certification process became quite complex, and would yield a very narrow certification. For a given piece of equipment, many separate certifications would be required (for its use with individual cleaning chemistries). Additionally, Ted Smith (Silicon Valley Toxics Coalition) voiced concern that certification of a dangerous chemistry could occur if it were used with the "right" cleaning system. For example, a cleaning formulation that could not pass the criteria as a wipe cleaning chemistry could potentially be certified when it was used

in a tightly sealed vapor degreaser. This concern was discussed at length by the Panelists. They concluded that while appropriate theoretical limits could be set on emission and exposure parameters for chemistries used with new and properly maintained equipment, "real world" emissions and resulting exposures would, in all likelihood, be higher in many shops, due to poor equipment maintenance.

The second alternative for criteria scope was to develop one set of criteria for cleaning chemistries and a separate set for cleaning equipment. This would facilitate the development of a more universal, easily applied set of criteria. A detriment to this approach was its inability to capture genuine chemistry/equipment use combinations. The primary efforts of the Panel focused on developing criteria for the chemistries and a detailed set of recommendations was developed. Panelists also discussed criteria addressing cleaning equipment and developed a set of preliminary recommendations, that require considerable further effort. (Members suggested forming a panel with different skill sets than those needed for developing the cleaning chemistry criteria.) The resulting preliminary equipment recommendations are included later in this report.

Stringency of Criteria

Panel members generally agreed that the major aim of this project was to develop criteria to help achieve greater pollution prevention and reduce the risks to human health and the environment. Panel members debated, however, the level of difficulty the criteria should create. Extremely strict criteria would allow only products presenting the most minimal risks to be certified. If few products could pass such strict criteria, the overall utility and environmental benefit of the program would be extremely low. If approval were too easy to attain, the desired screening effect of the criteria would be lost, and very questionable products would attain certification. This, too, would minimize the overall utility and benefit of the program.

The Panel recognized that a primary program goal must be to maximize the utility of the criteria. Many agreed that it was important to adjust criteria stringency to attract many Applicants to the program, and allow a sufficient number of products to be certified. (It was not clear how many certified products would constitute a "sufficient" number).

Flexibility of Criteria

Another continuing debate among Panel members concerned the degree of flexibility that should be reflected in the criteria. Would maximum benefit be achieved from a rigid set of criteria that could not be appealed—for which it would be very clear that some products passed and others failed? Would subjective criteria be better—for which a more holistic picture of the cleaning system could be developed, and many factors could be considered in certifying or rejecting it? Most of the panel agreed that some flexibility was needed in the criteria, especially in the more subjective areas, such as environmental impacts. This issue is discussed further in the GENERAL DISCUSSION POINTS section, under **Appeals**.

Quality of Data and Cost of Certification

The direct relationship between costs for a DTSC certification and the quality and quantity of data needed to evaluate a cleaning chemistry became an overriding consideration during the criteria development. DTSC representatives and Panelists representing small manufacturers strongly argued that if certification costs rose above a few thousand dollars, companies would be discouraged or prevented from applying.

This constraint became most important when the Panel considered how to handle a cleaning chemistry containing ingredients for which little or no health or environmental data exist. In an attempt to control certification costs, a fair amount of leeway in the gathering of health and environmental data was approved. The certification process would rely heavily on available information, with a lower necessity for companies to generate expensive toxicological data on their products. Application costs were divided such that the total cost would be paid in stages. The criteria were organized into these stages, each of which would require certain tests or assays. The stages requiring more expensive assays would follow those that were less expensive. Therefore, a product moving through the stages would undergo more expensive testing only after it passed the earlier stages.

How Many Levels of Certification Should be Issued?

The Panel discussed whether they should approve one or various classes of certification (e.g., good, better, best). Most members advocated a single type of certification, however, the topic resurfaced with discussion about claims a vendor could make with the certification and what the Expert Panel should do in circumstances with limited information. What should be done if a chemical is very effective in some areas, but not others? Kim Wilhelm (DTSC) suggested that granting a qualified certification could be useful in some instances. When a point of controversy arises regarding a particular product that has proven value but does not pass part of the criteria, DTSC would have the option to change the language of the claim, and issue a qualified certification. This approach has been successfully used in DTSC's ongoing Environmental Technology Verification program.

Understanding What Has and Has Not Been Certified

The Panel discussed the need for Applicants to understand the meaning of a DTSC certification, as well as the appropriate ways to use the certification in marketing and promoting their products. Kim Wilhelm stated that in his experience with the Environmental Technology Certification program, claims made by vendors following certification tended to be too broad (e.g., that a particular technology has "zero environmental impact").

The Need for Clear, Unambiguous Criteria and Manufacturers' Claims

Kim Wilhelm was concerned throughout the project that the criteria and certification statements meet Federal Trade Commission (FTC) guidelines for clarity, and that they not be misleading. Because of this importance, he circulated the FTC guidelines to the panel early in the project. Kurt Werner (3M Specialty Chemicals) suggested that the FTC guidelines for claims be incorporated into the application protocol.

II. Alternative Chemistries: Recommendations for Application and Evaluation Protocols

Certification Classes

Candidate chemistries will be evaluated to determine whether they qualify for an Alternative Cleaning Chemistry Certification, as well as to identify the class of certification that is appropriate for qualified chemistries. A cleaning chemistry is eligible for approval in one or more of the following classes of certification:

- **Precision metals cleaning:** for parts produced in close tolerance electroplating, machining, casting, and other types of metal fabrication operations.

- **Precision electronics cleaning:** for printed circuit board, semiconductor, and electronic component cleaning operations.

- **General purpose cleaning:** for less demanding applications such as automobile repair shop cleaning.

Filing Fees

The Applicant will pay an initial fee (to be determined) to submit the candidate cleaning chemistry for evaluation of the Stage A criteria described. Those candidate chemistries meeting Stage A criteria will then be evaluated against Stage B parameters. The Applicant will pay an additional fee based on any tests or assays required at Stage B. If a candidate chemistry is eliminated at Stage A, it is not advanced to Stage B, and the Applicant pays for the initial evaluations only. This approach avoids the problem of an Applicant paying full fee, and possibly having its chemistry eliminated early in the evaluation process.

Information Required from the Applicant

The following information is required at the time of application. Stage A processing will not commence until it has been provided in full.

- Name, address, phone number and fax number of Applicant, including the Applicant's contact person.
- Name of product.
- Formulation data sheet specifying ingredients to 0.1% (weight/volume).
- Materials Safety Data Sheet.

- Flash point data for the cleaning chemistry determined by either the closed cup Penske-Marten method, or the Setaflash method.
- pH data for the cleaning chemistry in its concentrated form.
- Name, address, and phone number of 10 shops in which the cleaning chemistry has been used for at least one year and is currently being used. Applicant must specify the contact person at each. Applicant should supply information on at least *three* shops using the cleaning chemistry in each application (precision electronics cleaning, precision metal parts cleaning, or general purpose cleaning) for which certification is desired.
- Complete vendor literature for the product (may include examples of product packaging and labeling). Should also include information on the types of soils that the cleaning chemistry is meant to remove, and any known surfacing materials incompatibilities.
- Sample of the candidate cleaning chemistry, in its concentrated form. Alternatively, if the candidate cleaning chemistry already holds an SCAQMD CAS certification, the Applicant will submit a copy of that certification, along with a copy of the test results from the SCAQMD laboratory.

(Note: All proprietary product information supplied by the Applicant, and labeled as such, will be treated in strict confidence.)

Optional Information from the Applicant

The Applicant can reduce the costs of Stage B screening by supplying as much of the following information as possible. The quality and acceptability of this information will be subject to approval by the Expert Panel, whose functions and membership are discussed below. In general, data generated by third-party laboratories will be preferred over in-house laboratory findings.

- *Toxicity data*
    - Acute lethality
    - Skin/eye irritation potential
    - Skin sensitization potential
    - Chronic toxicity/carcinogenicity
    - Developmental/reproductive toxicity
    - Mutagenicity
- *Environmental toxicity data*
    - Ceriodaphnia bioassays
    - Fathead minnow bioassays
    - Green algae bioassays
- *Biodegradability data*
    - BOD
    - COD
    - Ready Biodegradability (US EPA, Office of Prevention, Pesticides and Toxic Substances Guideline 835.3110)

The Expert Panel

The Stakeholder Panel agreed that for the certification program to be successful, it must have available a group of specialists charged with the tasks of evaluating data submitted by the Applicant, conducting the necessary site inspections, and making certification decisions on all subjective aspects of the criteria. Such a panel must also assess an Applicant's data quality, decide what types of additional testing may be necessary, and rule on appeals. This group would have special expertise in areas such as environmental science and engineering, municipal wastewater treatment, environmental and human toxicology, industrial hygiene, organic chemistry, and possibly other fields as well. The more stable the membership of such as panel was, the more it would help to ensure consistent application of the criteria.

Kim Wilhelm noted the difficulty in determining payment to the Expert Panel members. The precedent for current Environmental Technology Verification is for internal DTSC staff to handle decision making, bringing in additional experts when needed. Establishing a core Expert Panel would require recruiting individuals for an extended time and keeping them on retainer at professional fee levels to assure their availability. Kim commented that, DTSC is required by law to recover the actual costs of the certification program; therefore, the funding level available for an Expert Panel would depend on the number of Applicants for the certification.

Collaboration with South Coast Air Quality Management District (SCAQMD)

The criteria described below include the requirements of SCAQMD's Clean Air Solvent (CAS) Certification Protocol. The laboratory analyses necessary to verify compliance will be performed by SCAQMD, or, if a reciprocal laboratory agreement is formed, at a DTSC laboratory. The analyses can also be performed at SCAQMD-approved private laboratories. The test protocol will be uniform at all laboratories verifying compliance.

DTSC will forward a sample of the candidate cleaning chemistry, in its concentrated form, to the analysis laboratory. The analysis laboratory will evaluate the sample for Volatile Organic Hazardous Air Pollutants (VOHAPs), Ozone Depleting Compounds (ODCs), Global Warming Potential compounds (GWPs), reactive components, and total Volatile Organic Compound (VOC) concentration. The SCAQMD laboratory's detection limit for compounds fitting the above categories is **0.01%** of the concentrated form of the cleaning chemistry. Alternatively, if the candidate cleaning chemistry already holds an SCAQMD CAS certification, the Applicant will submit a copy of that certification, along with a copy of the test results from the SCAQMD laboratory.

If a CAS certificate issued by SCAQMD is later revoked by that agency, any alternative solvent certification issued by DTSC would also be revoked.

III. Discussion Of Alternative Cleaning Chemistry Recommendations

In preparing the criteria recommendations, the authors attempted to capture as accurately as possible the consensus opinions of the Stakeholder Panel and its guests. When divergent opinions could not be reconciled, the authors attempted to represent the dominant opinion in the recommendation. In the pages that follow, each criterion recommendation is followed by a summary of the discussion, differing viewpoints, and range of opinions expressed by the participants.

The criteria recommendations below apply to **industrial** cleaning rather than consumer cleaning applications.

Two stages of criteria are suggested. Stage A includes "**Make-or-Break**" criteria, which provide an initial screen for eliminating cleaning chemistries that are perceived to pose an unacceptable risk to human health or the environment. The Make-or-Break criteria are simple, easily applied discriminators, and employ readily available information. Also included in Stage A are criteria that use anecdotal evidence to verify that the chemistry is able to achieve a high level of performance, and vendor literature to verify that the vendor has met its responsibilities for clear operating instructions and accurate information on hazards associated with the chemistry.

Stage B criteria involve more in-depth analyses of the candidate cleaning chemistry, employing biological and environmental assays, data-base research, and/or toxicological modeling approaches.

STAGE A: SCREENING CRITERIA

Stage A. 1.0 Make-or-Break Criteria

The make-or-break criteria include all SCAQMD CAS requirements, which focus on air quality, as well as other requirements covering releases to other media. Make-or-Break criteria are grouped into the following areas of concern:

- Global environmental impacts.
- Regional environmental impacts.
- Human health impacts.
- Cautionary substances.

A. 1.1 Global Environmental Impacts

A. 1.1.1 Ozone Depletion Potential (SCAQMD Clean Air Solvent Requirement)

Criterion recommendation: *No cleaning chemistry shall be certified when it contains more than 0.01% of chemicals that are stratospheric ozone depleting compounds (ODCs).* **Table 1**, developed by SCAQMD, lists known ODC's.

Discussion: The Stakeholder Panel and guests generally agreed on this criterion.

A. 1.1.2 Global Warming Potential (SCAQMD Clean Air Solvent Requirement)

Criterion recommendation: *No cleaning chemistry containing greater than 0.01% of chemicals on the SCAQMD* Compounds with Global Warming Potential *list shall be certified,*[2] *with the exception of CO_2 that is used in such a way as to not add to the net CO_2 inventory of the atmosphere.*[3] The SCAQMD list is included in **Table 2**.

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[2] This list was formulated from the following sources:

United Nations Environment Programme (UNEP), February 1995, *Scientific Assessment of Ozone Depletion: 1994*, Chapter 13, "Ozone Depleting Potentials, Global Warming Potentials and Future Chlorine/Bromine Loading."

Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-1994

[3] For instance, it would be acceptable to use CO_2 that is either taken from the atmosphere, or captured from the waste stream of another industrial process.

New cleaning chemistry: Convincing evidence must be presented that a new cleaning chemistry has a global warming potential (GWP) not greater than 100 (100 times greater than CO_2), integrated over a 100 year interval.[4]

Discussion: Participants disagreed whether it was better to integrate over a 100-year interval, or a shorter one. The general opinion was that integrating over the 100-year interval provided the better measure of the lasting effects of the cleaning compound.

3M suggested an alternative approach to judging compounds on their GWP. Kurt Werner stated that SCAQMD's lists do not rely on the best science currently available. He suggested use of the Total Equivalent Warming Impact (TEWI) approach for calculating global warming. This methodology considers both the direct contribution to global warming of greenhouse gases due to solvent emissions, and the indirect contributions attributed to carbon dioxide emissions resulting from energy consumed by the cleaning operation. The TEWI methodology is discussed in more detail in **Appendix I**. The information in this appendix was developed by Kurt Werner.

A. 1.2 Regional Environmental Impacts

A. 1.2.1 Volatile Organic Hazardous Air Pollutants (SCAQMD Clean Air Solvent Requirement)

Criterion recommendation*: No cleaning chemistry shall be certified when it contains more than 0.01% of chemicals on any of the following lists:*

- *"Hazardous Air Pollutants" (HAPs) list as contained in Section 112 (b)(1) of the 1990 Clean Air Act (used in the SCAQMD protocol).*
- *"List of Toxic Substances" in Section 313 of the federal Emergency Planning and Community Right-to-Know Act (EPCRA); or*
- *"Substances for Which Emissions Must be Quantified" list in Appendix A-I of Proposed Amendments to the Emission Inventory Criteria and Guidelines Report Published in Accordance with the Air Toxics "Hot Spots" Information and Assessment Act of 1987 (AB 2588).*

Lists two and three above are included in these criteria, but are not a part of the SCAQMD protocol. All three of the lists noted above are included in **Tables 3, 4, and 5.**

Discussion: In early drafts of this criterion, only the HAPs list was included. Participants mentioned that this list was not as comprehensive or as current as some others. Kathleen Wolf

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[4] For the sake of comparison, 1,1,1-TCA has a GWP (100-year integration) of 110.

(IRTA) suggested the use of AB 2588 because it was updated more often. The EPCRA list was chosen for its focus on problematic compounds in effluents from industrial processes. The Panel believed that this would capture a different realm than does the air toxics lists.

The Panel noted that the criteria should be structured to respond automatically when any one of the reference lists changes.

A. 1.2.2 Reactivity (SCAQMD Clean Air Solvent Requirement)

Criterion recommendation: *No cleaning chemistry shall be certified when it contains more than 0.01% of chemicals on the "Maximum Incremental Reactivity" (MIR) list (**Table 6**). The chemicals on this list all have MIR values higher than toluene. This list is derived from SCAQMD's CAS protocol, and from Appendix VIII of the California Air Resources Board's California Exhaust Emission Standards and Test Procedures for 1988 and Subsequent Model Passenger Cars, Light-Duty Trucks and Medium-Duty Vehicles, as amended on September 22, 1993.*

Discussion: The Panel and guests were in general agreement on this criterion.

A. 1.2.3 VOC Content and Partial Pressure (SCAQMD Clean Air Solvent Requirement)

Criterion recommendation: *No cleaning chemistry shall be certified when, at its normal working strength (as specified in the manufacturer's instructions for its use), it contains a volatile organic compound (VOC) content greater than 50 grams/liter. VOC content will be determined by SCAQMD using its Method 313-91, Determination of Volatile Organic Compounds (VOC) by Gas Chromatography/Mass Spectrometry (GC/MS).*[*]

If the VOC content is less than 50 grams/liter, no cleaning chemical which, at its normal working strength, has a VOC composite partial pressure (CPP) greater than 5 mm Hg at 20 ^{o}C will be certified.

See the **Appendix II** for details of the GC/MS methodology. CPP will be determined using the formula in Section (b)(43) of SCAQMD's Rule 1171.

Discussion: In early discussions, the Panel generally agreed to use 50 grams/liter as a maximum allowable VOC level for compounds to be certified, based on the SCAQMD protocol. Members discussed alternative VOC measurement technologies at length; SCAQMD was having similar discussions. Some participants questioned whether EPA Method 24 was the best approach for VOC analysis. The SCAQMD chemistry staff suggested that it was of questionable accuracy when determining VOC content below 100 grams/liter. A theoretical calculation of VOC content determined from manufacturer-supplied composition data (per product) was also considered. This approach was rejected, as its accuracy depends on data supplied by the manufacturer.

The approach ultimately adopted, SCAQMD's Method 313-91 (based on GCMS analysis), was accepted by the Panel as far more reliable than alternative methods. Z Halar (Inland Technology) inquired whether the high temperatures used with this method would volatize surfactants, causing them to register erroneously as VOCs. To answer his question, SCAQMD chemists tested Inland Technology and Brulin cleaning chemistry samples containing surfactants. As expected, tests showed that they did not exceed the 50 g/L limit. Additionally, the method produced consistently reproducible results, and could measure VOC levels lower than 1 g/L (lower detection limit approximately 0.1 g/L).

A. 1.3 Human Health Impacts

A. 1.3.1 Carcinogens

Criterion recommendation: *No cleaning chemistry shall be certified if, in its concentrated form, it contains more than 0.01% of a component on any of the following lists:*

- *IARC Group 1 or Group 2A or 2B[5] chemicals*
- *National Toxicology Program (of the National Institute of Environmental Health Sciences) "Known Carcinogens" or "Reasonably Anticipated to be Carcinogens" lists.*
- *California Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65" - Title 22, California Code of Regulations, Sections 12705 and 12709) list entitled "No Significant Risk Levels for Carcinogens"*

The lists referenced above are reproduced in **Tables 7, 8, and 9A**.

Discussion: The proper threshold concentration for a carcinogen (above which the cleaning chemistry would not be certified) was debated at length. Arguments were based on the

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[5] IARC Group 1 refers to known human carcinogens. IARC Group 2 refers to suspected human carcinogens. Definitions of the IARC groups are as follows:

Group 1: The agent (mixture) is carcinogenic to humans. The exposure circumstance entails exposures that are carcinogenic to humans.
Group 2 (two classifications):
Group 2A: The agent (mixture) is probably carcinogenic to humans. The exposure circumstance entails exposures that are probably carcinogenic to humans.
Group 2B: The agent (mixture) is possibly carcinogenic to humans. The exposure circumstance entails exposures that are possibly carcinogenic to humans.
Group 3: The agent (mixture, or exposure circumstance) is unclassifiable as to carcinogenicity in humans.
Group 4: The agent (mixture, exposure circumstance) is probably not carcinogenic to humans.

precedents set by other groups for de minimus levels of carcinogens, and on reasonable and cost-effective levels that manufacturers and formulators could meet.

Various panel members suggested that typical de minimus levels were 1.0% for noncarcinogens and 0.1% for carcinogens. The threshold level was set at 0.1% in preliminary drafts of this criterion. At the last meeting, however, Ted Smith (Silicon Valley Toxics Coalition) remarked that 0.1%, or 1000 PPM, could be in conflict with certain health standards. He stated that Massachusetts law limits concentrations to 0.01%, which is ten times more restrictive and (in his opinion) considerably more protective of human health. He asserted that the SCAQMD protocol uses threshold levels of 0.01% for chemicals. The Panel concurred, and the threshold level in the criterion recommendation was set at 0.01%.

A major concern in setting a de minimus level was related to the frequent presence of unintended compounds in a cleaning chemistry. Such compounds are often feedstock contaminants, byproducts of synthesis processes, or result from cross-contamination of different products. Mike Beeks (Brulin Corporation) noted the difficulty in eliminating small concentrations of such chemicals. Z Halar (Inland Technology) used ethylene oxide, an IARC listed carcinogen, as an example. Ethylene oxide is an intermediary compound in the synthesis of many surfactants, hence an inescapable contaminant of many cleaning chemistries. A more strict threshold level of 0.01% would, however, help to limit variations in product composition due to different feedstocks or cross-contamination of different products. Z Halar thought that his company could meet the more restrictive standard. Further discussion of product quality issues can be found under the Product Quality entry in the **General Discussion Points** section following section B 3.0.

Participants were concerned that the criteria might allow certification of cleaning chemistries containing "Prop 65" chemicals. The Panel agreed that eliminating cleaning chemistries containing **any** chemical on the Prop 65 (*California Safe Drinking Water and Toxic Enforcement Act of 1986*) list would be extremely restrictive, and not necessary. Prop 65 labels on chemicals are meant to serve as warnings to use the chemicals with care; they are not meant to discourage use of those chemicals altogether.

A. 1.3.2 Reproductive Toxicants

Criterion recommendation: *No cleaning chemistry shall be certified when it contains a component in a concentration greater than **0.01%** of the concentrated form of the cleaning chemistry and is listed in the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) table entitled "Acceptable Intake Levels for Reproductive Toxicants."*

Table 9B contains copies of these lists.

Discussion: As with carcinogens, the threshold level for reproductive toxicants was changed from 0.1% to the more restrictive 0.01%.

A. 1.3.3 Fire and Explosion Hazard

Criterion recommendation: *The flashpoint of the concentrated form of the cleaning chemistry must be not less than 140 degrees F. Furthermore, the flashpoint of the concentrated form of the cleaning chemistry must be not less than 40 degrees F above the manufacturer's recommended usage temperature. Flashpoints shall be measured using either the closed cup Penske-Marten method, or the Setaflash method.*

Discussion: The Panel and guests generally agreed on this criterion.

A. 1.3.4 Corrosivity and Causticity

Criterion recommendation: *No cleaning chemistry having, at its most concentrated recommended working strength (as specified in the manufacturer's instructions), a pH either below 2.5 or above 11 shall be certified.*[6]

Discussion: The pH criteria was designed as a simple guideline for reducing risks of splash injuries to the eyes and skin of workers using the cleaning products. The need for this type of criteria was emphasized by Dr. Jim Seward, an occupational medicine physician and head of LLNL's Health Services Department. He mentioned that eye-damage accidents were the most common solvent-related occurrences he sees in emergency rooms.

Some Panel members argued that if a manufacturer's instructions regarding personal protective equipment were followed, then this criterion would be unnecessary. It was recognized, however, that personal protective equipment advisories are often ignored.

Grant's *Toxicology of the Eye* guided this criterion. It specifies the pH levels likely to lead to irreversible damage. The threshold for permanent eye damage generally lies between 11 and 11.5 for alkaline solutions and 2.0 and 2.5 for acid solutions. Initially, the Panel set the acceptable pH range for this criterion from 2 to 11. Later the lower pH limit was revised to 2.5 to make the criterion more protective.

Exceptions to these guidelines were discussed. Sodium metasilicate, for example, has a pH higher than 12, but generally does not cause permanent eye damage. In such cases, an appeal could be made. Other Panelists opined, however, that a single, non-appealable criterion would

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[6] According to Grant's *Toxicology of the Eye*, the danger range for alkaline pH begins at 11 and increases markedly at 11.5. For acids, it begins at 2.5, much worse at 2 or below. For alkaline solutions, pH of 11 or below generally cause "only slight and reversible injury to the corneal stroma on brief (10 minute) exposure." <page 60> For acidic solutions: "Applied to human eyes, solutions from pH 7 down to pH 2 induce an increasingly strong stinging sensation, but on brief contact cause no damage." <Page 46> Grant, W. Morton, *Toxicology of the Eye*, Third Edition, Springfield, IL, 1986.

be best. It would simplify the evaluation of candidate cleaning chemistries, and minimize costs involved in the certification process.

Some solvents having neutral pHs can still present considerable dangers to the eye or skin. For some solvents, pH cannot be measured. In such cases, applying protocols for eye irritation endorsed by the United States Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances (OPPTS), or the Organization for Economic Cooperation and Development (OECD) may be useful.

Note: OPPTS and OECD health effects protocols generally involve animal testing. The Stakeholder Panel recognized the increasing public opposition to generating toxicity data through the use of animal testing.

A. 1.3.5 General Health Hazard

Criterion recommendation: *No cleaning chemistry shall be certified when its concentrated form contains more than **0.01%** of any material with a National Fire Protection Association (NFPA) Health Hazard rating of either 3 or 4.*

The NFPA's *Fire Protection Guide to Hazardous Materials* (11th Edition, page 704-11) defines these NFPA ratings as follows.

- A Health Hazard rating of 3 corresponds to "materials which on short exposure could cause serious temporary or residual injury."
- A Health Hazard rating of 4 corresponds to "materials which on very short exposure could cause death or major residual injury."

Discussion: As with the Carcinogenicity and Reproductive Toxicant criteria, the threshold level was changed to 0.01%, to make this a more protective criterion.

Some Panel members suggested using the HMIS rating instead of the NFPA ratings, because they believed that the NFPA ratings focused only on fire situations. The NFPA *Fire Protection Guide to Hazardous Materials* states, however, that its Health Hazards ratings are "intended to clearly describe the effects of acute (short-term, high level) exposure to each chemical by physical contact, eye or skin absorption, or inhalation" (page 49-144).

A. 1.4 Cautionary Substances

A. 1.4.1 Halogenated Cleaning Compounds

Criterion recommendation: *No cleaning chemistry containing halogenated (chlorinated, brominated, iodized, or fluorinated) organic compounds of any kind will be certified, unless convincing evidence can be presented that the potential environmental impacts (including ozone depletion and global warming potentials) and health impacts (including acute and chronic health effects) are insignificant.*

Discussion: Representatives from 3M advised Panelists that the present halogenated compounds criterion be dropped or significantly modified to create a more "level playing field" for substances such as hydrofluoroethers (HFEs) compared to other alternative cleaning chemicals. The 3M representatives argued that the properties of HFEs are quite different than those of such chlorinated substances as TCE, 1,1,1-TCA, or a variety of CFCs; and that these differing properties render the HFEs safer and of lower risk to the environment. John Butenhoff, a 3M toxicologist, pointed to the lower lability of the carbon-halogen bond in HFEs as an indication of their decreased reactivity in the environment.

At the September, 1997 meeting, Kurt Werner of 3M proposed that the criterion be rewritten as follows.

"*Cleaning chemistries containing halogenated (chlorinated, brominated, iodized, or fluorinated) organic compounds of any kind will not be certified, unless convincing evidence can be presented that the compound will help reduce health and environmental risks associated with industrial cleaning operations without compromising cleaning performance.*"

3M participants asserted that this criterion stands out from the others in that it eliminates an entire class of chemicals, not by evaluating a specific chemical property, but ostensibly for political or emotional factors.

In general, Panel members believed that the present criterion recommendation was appropriate. Some argued for eliminating the appeals provision for certifying a halogenated compound. Concern was expressed that researchers don't yet know enough about the environmental and health effects of these new halogenated compounds, and that DTSC should be extremely careful in certifying such chemicals. It was also mentioned that although HFEs may indeed present low risk, in the presence of high temperatures (as occurs during a fire), they may degrade into extremely dangerous compounds such as hydrogen fluoride.

Stage A. 2 criteria will be applied to cleaning chemistries meeting Stage A. 1 criteria.

Stage A. 2.0 Performance Verification

Criterion recommendation: *Manufacturers pursuing certification of their cleaning chemistries must provide the names, addresses and phone numbers of, and points of contact in, at least ten shops currently using the cleaning chemistry*[7]*. These shops must be satisfied with its performance. Applicants should select facilities that represent:*

- *a wide spectrum of shop sizes,*
- *various numbers of employees, and*
- *different cleaning methods.*

It is advisable that both large and small businesses be included, as well as both manual and automated cleaning operations. Several types of cleaning application equipment would be represented – sprays and immersion baths, closed and open systems – ,depending on the nature of the certification(s) sought by the Applicant.

When contacted by the Expert Panel, the points of contact in the shops will be requested to provide information on their operations involving the cleaning chemistry. The Expert Panel will ask about the materials being cleaned, how the cleaning chemistry is delivered, the level of cleanliness achieved and other similar questions.

Note: All proprietary product information supplied by the Applicant, and labeled as such, will be treated in strict confidence.

Besides verifying that the candidate system can be used successfully, these data will identify the particular types of applications (precision electronics cleaning, precision metal parts cleaning, or general purpose cleaning) for which the chemistry is suitable. Of the ten or more shops supplied, the Applicant should supply information on at least three shops using the system in each application for which certification is desired. (For instance, if certification of the system as a precision metal parts cleaning chemistry is desired, then at least three shops using the system in this way should be provided).

Discussion: Throughout the criteria development process, lengthy discussion ensued regarding the method for verifying cleaning chemistry performance. Some Panel members implied that poor cleaning chemistries would be certified unless the criteria screened for performance, damaging the utility of the certification program. José Camahort (Lockheed-Martin Missiles and Space Corporation) and other Panel members stressed the difficulty in developing criteria for cleaning chemistry performance, however, because performance is extremely application-specific. In many industries, no set standard or methodology exists for measuring cleaning performance. Where methodologies do exist, a cleaning performance test for one industry will likely not be a valuable predictor of efficacy in another application. José Camahort explained that, regardless of the published performance data, most companies would test the cleaning chemistry for their specific applications. The Panel concluded that specific performance standards would not be useful in the certification protocol. They decided instead to focus on

[7] The shops must be using the cleaning chemistry in a manner consistent with manufacturers' instructions and cautions.

obtaining and evaluating anecdotal performance information from industries in the certification class the Applicant requested.

Stage A. 3 criteria will be applied to cleaning chemistries meeting Stage A. 2 criteria.

Stage ***A. 3.0 Vendor Responsibility***

Criterion recommendation: *Vendor instructions for using a cleaning chemistry must include clear directions on the proper, safe use of that cleaning chemistry. Instructions must include information on the appropriate application equipment and personal protective equipment required for safe use of the cleaning chemistry. A chemistry will be certified for use only with the appropriate equipment.*

Vendor literature must include information on the possible hazards of using the chemicals. The literature must specifically include information on skin and eye irritation and skin sensitization, and precautions to observe when using the chemicals. The vendor must also specify instructions for proper recycling and/or disposal of waste generated during normal use of the cleaning chemicals.

Consideration will be given to the manufacturer's or distributor's recommended handling/disposal options for spent cleaning chemicals. Preference will be granted to cleaning chemicals that can be readily recycled or regenerated (provided that recycling capacity or technology is available at a reasonable cost). Recommendations for final disposition of spent material must clearly state whether: it must be managed as a hazardous waste; it can be sent to the sewer; pre-treatment is recommended; the material can be recycled; it can be landfilled. Guidance must not be misleading. For instance, claims that a cleaning chemistry is "biodegradable" should state explicitly whether they apply to the cleaning chemistry alone, or the cleaning chemistry and any foreign materials added during use. the recommendations must also specify any regulatory agencies to be consulted prior to final disposition of the spent cleaning chemistry. For example, instructions might read, "Before releasing this product to the sewer, contact your local waste water sanitation agency."

Product quality: It is important that the vendor guard against changes in the chemical composition of the cleaning chemistry that may alter its properties. These changes may come from variations in feedstock, or inadvertent mixing of different products. A certification will be issued only for a specified chemical composition. If a product's chemical composition is varied in any way, either intentionally or unintentionally, then the certification will no longer apply.

While not required for certification, it is strongly encouraged that vendors:

- *conduct short seminars for customers on safe use, handling, and disposal; and*
- *develop a "closed loop" recycling option for the wastes generated during normal use of their products. Vendors are encouraged to accept responsibility for how the product is used, and how the wastes are handled as well. A "total service concept" could be offered by the vendor, in which spent cleaning chemicals are collected and reconstituted or processed for disposal by the vendor. (Note: The vendor must have the proper hazardous waste permits in order to offer such an off-site recycling option to the user shops.)*

Discussion: There was considerable discussion on the issue of product quality. The Panel recognized that changes in raw materials can affect the chemical composition of the cleaning chemistry, as well as its properties. Manufacturers who buy feedstock from multiple suppliers can experience significant variations in the composition of their ingredients. Z Halar (Inland Technologies) indicated that manufacturers frequently change suppliers. (Small manufacturers

driven to minimize the costs of ingredients look for the cheapest source, and may change suppliers once a year or more.) The Panel felt strongly that certification should be issued only for a cleaning chemistry with a specified chemical composition. The certification should be written such that if a product's chemical composition were varied in any way, either intentionally or unintentionally, the certification would no longer apply. It might be necessary for the certification to specify detailed acceptable chemicals compositions. A certified product might also be required to use only certain suppliers for its feedstocks.

The group questioned how the Expert Panel would determine if the product actually contained only the chemicals specified by the manufacturer, and in the concentrations claimed (It is not envisioned that application fees could cover extensive testing to determine the presence of problematic chemicals.) It would probably be necessary to rely on manufacturers' data to make certification decisions. Z Halar suggested that in addition, it may be practical to test cleaning products for certain specific chemicals that are likely contaminants of a particular formulation (e.g. ethylene oxide in surfactants).

Chemical handling and mixing at the formulator's facility is another issue related to product purity. The Panel debated how the certification process would catch out-of-spec formulations resulting from poor quality control practices such as improperly flushing supply lines between different product formulations. Z Halar indicated that even large companies have issues of cross contamination and multi-use lines, and said that spot-checking at the formulator, supplier, and distributor levels is the only way to control this. The Stakeholder Panel had concerns about the Expert Panel being involved in the vendor's quality control protocols. Pom Pom Ganguli (SCAQMD) suggested that random field audits be performed within the five-year period of the certification. Tom Barron (Thomas S. Barron, P.E.) added that these verification measures are absolutely essential. He recommended taking random samples from unopened, sealed product bottles.

Stage A. 4 criteria will be applied to cleaning chemistries meeting Stage A. 3 criteria.

Stage ***A. 4.0*** ***Site Inspection***

Criterion recommendation: *At least **three** California facilities employing the cleaning chemistry will be selected by the Expert Panel for inspection by at least one Expert Panelist. (The entire Expert Panel, however, will evaluate the data collected.)*

For each Certification Class sought (precision metal cleaning, precision electronics cleaning, or general purpose cleaning), at least one facility employing that particular type of cleaning will be inspected. Selected facilities will represent a wide spectrum of shop sizes, numbers of employees, and cleaning methods. It is advisable that both large and small businesses be included in the inspections, and both manual and automated cleaning operations be examined. Ideally, the Expert Panel would examine several types of cleaning application equipment – sprays and immersion baths, closed and open chemistries, etc.

Expert Panelists will observe practical applications of the product to identify any environmental and health issues not captured in previous criteria. The visit will also serve to verify users' comments on performance of the cleaning chemistry. Such issues may require that additional cautions or instructions be included in the manufacturer's product literature.

The inspector should attempt to answer the following questions.

- *Does the cleaning chemistry exhibit any environmental or health problems (e.g., unpleasant odors or rashes) that are not identified in vendor literature,?*
- *Are the cleaning chemistry use instructions clear and easy to follow?*
- *Are disposal instructions clear?*
- *Does the cleaning chemistry perform as required?*
- *Does it adequately replace currently used materials?*
- *Do any quality problems result from the use of this cleaning chemistry?*
- *Do users accept the cleaning chemistry for its stated uses?*
- *Does use of the cleaning chemistry change the nature of products being manufactured? Are these changes important to the customers who buy the products?*
- *Are changes required in the equipment, work procedures, or other chemicals already in use when the shop first adopts the cleaning chemistry? Do these changes have an impact on productivity or profitability?*

Discussion: The Panel and guests generally agreed on this criterion.

STAGE B: ASSAYS, DATABASE SEARCHES AND MODELING

Stage B criteria will be applied to candidate cleaning chemistries that have successfully passed Stage A criteria. Stage B criteria involve data generated in biological or environmental assays. Before Stage B begins, the Applicant will be apprised of the cost of the assays and tests deemed necessary by the Expert Panel, and may choose to proceed with or halt the certification protocol.

Quality of data

The Expert Panel will examine all assay data provided, to establish that proper laboratory procedures were followed. Data more than ten years old will be scrutinized particularly closely. Information on the testing laboratory and its procedures will be collected and reviewed.

Stage B. 1.0 Acute Toxicity

Criterion recommendation: *A candidate cleaning formulation must satisfy either Section B. 1.1 or B. 1.2, or both.*

B. 1.1 Mammalian Toxicity Assay

Criterion recommendation: *The Applicant must present data indicating that the **complete cleaning formulation**, at either its concentrated or typical working strength (as specified in the manufacturer's instructions for use), has passed an acute ingestive, dermal, or inhalatory mammalian toxicity assay. Passing "grades" for several common bioassays are given below. Bioassays should be performed according to conventional methods such as those endorsed by the United States Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances (OPPTS), or the Organization for Economic Cooperation and Development (OECD). Equivalent results from other mammalian bioassays can be submitted, and will be examined by the Expert Panel as possible substitutes for the tests described below.*

A cleaning formulation passes the acute toxicity criterion if it meets any of the following conditions[8]:

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[8] These conditions were formulated from data in:
Walker, J.D., "Estimation Methods Used by the TSCA Interagency Testing Committee to Prioritize Chemicals for Testing: Exposure and Biological Effects Scoring and Structure Activity Relationships." *Toxicology Modeling,* Vol. 1, No. 2, 1995, pp 123-141, and
US EPA *Health Effects Test Guidelines OPPTS 870.1200 - Acute Dermal Toxicity.* US EPA Office of Prevention, Pesticides, and Toxic Substances, EPA 712-C-96-192 (Public Draft), June 1996.

a. When administered orally to rats it exhibits a median lethal dose (LD_{50}) equal to or exceeding 500 milligrams per kilogram of body weight.

b. When administered by continuous dermal contact for 24 hours with the bare skin of albino rabbits or other common test species such as rats or guinea pigs, it exhibits a median lethal dose (LD_{50}) equal to or exceeding 50 milligrams per kilogram.

c. When administered in air by continuous inhalation for one hour to rats it exhibits a median lethal concentration (LC_{50}) equal to or exceeding 50 milligrams per liter.

B. 1.2 Alternative Evidence

Criterion recommendation: *When data on the complete cleaning formulation is not available or practical to obtain, the Applicant must then present evidence that* ***each of the chemical components*** *in the cleaning formulation passes one of the above conditions.*

Discussion: The Panel extensively discussed the definition of the Acute Toxicity criterion. Initially the group felt that it should be based on a risk assessment of the cleaning chemistry, as performed by the certifying laboratory and the Expert Panel. Exposure and toxicity data sets would be needed to perform such a risk assessment. The Panel was concerned about quantifying a worker's exposure to the cleaning chemistry during typical use.

The Stakeholder Panel and a smaller focus group including Michael Meltzer, Jim Seward, John Butenhoff, Katharine Gabor and several LLNL industrial hygienists, including Virginia Lew and Jim Johnson. discussed an approach for exposure studies. The focus group postulated that the certifying laboratory could establish several different use scenarios (including immersion baths, spray cleaning and wipe cleaning) and perform exposure measurements using personal exposure meters. An alternative method would generate mathematical models for the use scenarios. Models would combine the physical properties of the cleaning chemistry with assumptions regarding equipment and room parameters such as airflow and temperature.

Difficulties arose when the Panel considered the costs associated with making exposure measurements for every cleaning chemistry. These costs could easily become prohibitive. The modeling alternative became problematic when the Panel recognized the lack of generally accepted exposure models for industrial settings. Test results would be subject to challenge for each model. Furthermore, the Panel could not decide whether modeling with parameters representative of "normal" or "worst-case" scenarios was most appropriate. The Panel had difficulty balancing health and environmental protection against fairness to the cleaning chemistry manufacturers. Several Panel members also questioned whether the certification program should conduct abbreviated risk assessments of questionable value. Other agencies were judged to be far better suited for this task.
The complexity and cost of generating reliable exposure data contributed in part to the Panel's decision to recommend developing **separate** sets of criteria for cleaning chemistries and cleaning equipment.

The Panel also focused on developing toxicity criteria useful in screening cleaning chemistries, **independent of the equipment used to apply them**. Ideally, when setting criteria for either acute or chronic endpoints, data from an extensive "toxicity panel" would be available for the complete product formulation (rather than just for each component). It is not realistic, however, to expect an Applicant to provide such data. After the Panel reviewed the availability of toxicity information, it was clear that data on standard measures of acute toxicity (such as LD_{50}, or skin and eye irritation tests) are generally not available for cleaning chemistries. Chronic toxicity data are even more scarce. Often, toxicity data for individual components of a product are quite scarce as well. Initially, the Stakeholder Panel believed products lacking this information should not be certified. Katharine Gabor (LLNL) researched the costs of toxicity testing from sources including SRI International, Southern Research Frederick, and ManTech Environmental Technology. While they varied slightly, costs to generate a basic panel of acute toxicity data for a cleaning chemistry would cost at least several thousand dollars. Some panel members stated that such costs would make the certification process prohibitively expensive for small manufacturers of alternative cleaning chemistries.

The Panel generally agreed that toxicity criteria should be flexible enough to allow the Applicant to use various strategies for meeting certification requirements. Participants debated the necessity of obtaining acute toxicity information for the **complete cleaning chemistry**, versus acute data for **each ingredient**. The Panel strongly preferred **some toxicity data for the complete cleaning chemistry**, and this opinion is reflected in the criterion recommendation above. This recommendation does allow consideration of individual components as an alternative; however, the Applicant must show that **each** of the components in the formulation passes an acute toxicity bioassay.

The Panel also decided that data generated by bioassays, literature searches, or structure-activity-relationship models (discussed below) could be used for the certification.

In developing the acute toxicity criterion recommendation, an attempt was made to allow the Applicant considerable flexibility in gathering the necessary data. This would keep the application fee reasonable A wide range of acute toxicity data would be acceptable, enabling the Applicant to submit data already generated on its cleaning chemistry, rather than having to pay for new tests. The Expert Panel would carefully examine data quality, and accept only reliable results. Ron Block (Block Environmental, a bioassay laboratory) recommended caution in evaluating data generated more than ten years ago. The older methods were not as reliable as current ones.

The Panel was also concerned with data produced through animal testing. Mounting public opposition to the use of animal testing for generating toxicological data was mentioned several times.

Toxicological limits for acute oral toxicity, acute inhalatory toxicity, and for chronic toxicological parameters such as carcinogens, developmental toxicants, and mutagens were obtained from a methodology for "scoring" toxicological information developed by the Toxic Substances Control Act (TSCA) Interagency Testing Committee (ITC).[9]

One objection to the present criterion recommendation noted that without toxicity testing of **complete cleaning chemistry formulations,** the Panel has no means of evaluating the possible synergistic effects of chemical components in a cleaning chemistry. The Panel, while noting that this was true, preferred to allow the Applicant flexibility in collecting toxicity data. Panelists recognized that no single well-accepted modeling approach exists for estimating the toxicity of mixtures. They decided that if a general evaluation of the product by the Expert Panel, undertaken with "due diligence," revealed no evidence of synergism leading to increased toxicity, then evaluating toxicity data of the individual components would suffice for the certification program.

The Panel acknowledged that as more certifications are sought, the program will generate a database of information on the toxicities and environmental impacts of components commonly used in alternative cleaning chemistries. While initial toxicity data searches undertaken by the Expert Panel may be time-consuming, subsequent certifications should proceed faster and be less expensive as the database increases.

Stage B. 2.0 Chronic Toxicity

Criterion recommendation: *Cleaning chemistries containing at least **0.01%** of any chemical that has entered the industrial cleaning market within the last ten years (e.g., hydrofluoroethers, chlorobromomethane, fluoro-iodocarbons) must be examined in detail. These chemistries may not have been evaluated by organizations such as IARC or the National Institute of Environmental Health Sciences. For cleaning chemistries that have not been evaluated, additional data are needed.*

The Expert Panel may also find that certain older chemicals in a candidate cleaning chemistry have not been sufficiently evaluated as to their chronic toxicities. In this case, these chemicals, too, would be subject to this criterion.

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[9] Walker, JD "Estimation Methods Used by the TSCA Interagency Testing Committee to Prioritize Chemicals for Testing: Exposure and Biological Effects Scoring and Structure Activity Relationships." *Toxicology Modeling,* Vol. 1, No. 2, 1995, pp 123-141.

For each chemical of concern in a cleaning chemistry, the following information must be obtained, either through toxicological assays, literature searches, or through a modeling technique similar to the one described below. The data collected must indicate that, under the conditions of use specified in manufacturers' operating instructions, the toxicity of the chemicals appears to be low.

Rodent carcinogenicity (male and female mice and rats)
Developmental toxicity potential
Mutagenicity (Ames and/or Dominant Lethal Test)

B. 2.1 Metric for Interpreting Toxicological Results

Criterion recommendation: *The Interagency Testing Committee (ITC) methodology for "scoring" toxicological information will be used to evaluate chronic toxicity data.*[10] *In* ***Table 10****, toxicity ranges are defined and given scores of 0 to 3. A score of 3 corresponds to an extremely toxic substance, and 0 is the "best" score, indicating only slight toxicity. For a cleaning chemistry to be certified,* ***the toxicity of the chemical (established from either assays, literature search test data, or toxicological modeling) must be in a range that corresponds to a score of 0.***[11] ***A chemical scoring higher will be considered too high risk to certify.***

B. 2.2 Toxicological Modeling Approach

Criterion recommendation: *TOPKAT is a software modeling system used by such U.S. agencies as the EPA and the Food and Drug Administration, as well as by various corporations (CIBA-GEIGY, 3M, Bristol-Meyers, Clairol, Sandoz, and many others). It computes expected toxicological and environmental effects, based on the molecular structure of a chemical. It utilizes quantitative structural activity relationship (QSAR) methodologies, and is currently employed at LLNL and other national labs and universities. Using TOPKAT, a chemist requires about four hours to estimate the above parameters for each chemical. If a modeling technique is requested by the Applicant, either TOPKAT or a similar modeling method must be employed. The Expert Panel will determine if an alternative model is sufficiently reliable to generate meaningful data for the certification.*

Discussion: The chronic toxicity criterion screens cleaning chemistries for potential carcinogenic or reproductively toxic ingredients not caught by the Make or Break criteria. While chronic test data are very important, their availability for cleaning formulations is limited. The extremely high cost and study time associated with chronic bioassays makes them impractical for most

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[10]Walker, JD "Estimation Methods Used by the TSCA Interagency Testing Committee to Prioritize Chemicals for Testing: Exposure and Biological Effects Scoring and Structure Activity Relationships." *Toxicology Modeling,* Vol. 1, No. 2, 1995, pp 123-141.

[11] For carcinogenicity and developmental toxicity, a score of 0 indicates negative results in two animal species. For mutagenicity, a score of zero corresponds to negative results in more than one system.

companies. The Panel discussed structure activity relationship (SAR) models, particularly TOPKAT, for estimating chronic toxicological parameters. As with acute toxicity data, the Panel agreed that the chronic toxicity data for each component of a cleaning chemistry could be used in lieu of data for the complete formulation.

TOPKAT uses a series of databases and SARs to estimate the chemical toxicity. The model estimates toxicological parameters for single chemicals, not mixtures. The model is run on a personal computer, and various modules estimate different toxicological parameters. Each module costs approximately $10,000. Parameters that may be modeled include carcinogenicity, mutagenicity, developmental toxicity and some acute measures. TOPKAT is used by many agencies, labs, universities and corporations. John Butenhoff (3M) and others affirmed that TOPKAT is one of the better modeling programs available, and that the module predicting carcinogenicity is somewhat better developed than others (such as the one predicting developmental toxicity). John Butenhoff emphasized that the model is better used as a screening tool, than the final arbiter of a substance's carcinogenicity. The Panel agreed that TOPKAT or other "scientifically validated" or "generally accepted" QSAR models may be employed to meet data requirements for the criteria.

The chronic toxicity criterion recommendation originally applied to **new** chemicals. Kurt Werner (3M) challenged this premise. He suggested that chemicals that have entered the market within the past 10 years have actually had **more** review, with better evaluation techniques, than older chemicals. Simply because a chemical has been used for several decades, the Panel should not assume it has been accurately evaluated. On the basis of his comment, this criterion was changed to apply as well to older chemicals which, in the opinion of the Panel, have never been sufficiently evaluated as to their chronic toxicities.

Stage B. 3.0 Environmental Impact

Criterion recommendation: *Environmental risks not adequately investigated in Stage A may also be investigated. The Expert Panel will determine the necessity of collecting additional environmental impact data on the product before issuing a certification. The Expert Panel may require additional testing of the product, additional information from the vendor, or a modification in the manufacturer's instructions for use. Panelists will consider likely use scenarios of the product, as well as potential release pathways of the wastes generated. They will examine such parameters as the product's biodegradability, its potential for bioaccumulation, and the impacts of any substances such as chelating agents and biocides. Breakdown products will also be considered. Concerns may be raised if the cleaning chemistry's structure is similar to known "problem" chemicals. New chemicals will receive particularly careful scrutiny.*

Discussion: At the beginning of the criteria development process, an extensive list of environmental considerations was identified. Global and regional environmental impacts such as ozone depletion, global warming potential and reactivity (a measure of a chemical's potential to form smog) were addressed in the make-or-break criteria. The Panel generally thought that

the Environmental Impact criterion should address issues of aqueous toxicity, biodegradability, bioaccumulation, and eutrophication.

Panelists reviewed the methods and costs of environmental testing. Ron Block (Block Environmental Services) presented an extensive discussion of the protocols and expenses for various bioassays assays: fish survivability, LD_{50} tests, sediment bioassays and biodegradation. The Panel noted the lack of a consistent standard for identifying an increased level of environmental risk.

Dr. Alex Ekster of the San Jose/Santa Clara Wastewater Treatment Plant discussed chemicals of concern at POTWs. He expects that, due to its large capacity, his plant probably will not be severely impacted by an increasing volume of aqueous cleaning chemistries containing surfactants and detergents. (This influent causes problems at some plants due to foaming, and is typically managed through the addition of expensive cationic polymer defoamers.) Dr. Ekster indicated that the San Jose/Santa Clara plant is more concerned with organics, pesticides, halogens, and heavy metals. John Mukhar, from the same facility, cited biodegradability as a significant concern. If a cleaning chemistry doesn't degrade under publicly owned treatment works processes (POTW), it may accumulate in the body of receiving water (e.g., San Francisco Bay). Additionally, because soil does not biodegrade, cleaning chemistries can also accumulate there and cause problems.

The Panel discussed developing criteria on product life cycle issues such as the energy used in a cleaning system, or during the entire life of the cleaning chemistry. Members decided that there is no consistent, widely accepted method for examining product life cycle issues.

Mike Callahan (Jacobs Engineering Group) asserted that no cleaning chemistry should be certified if its intended disposal pathway is a storm drain or body of surface water. John Mukhar (San Jose/Santa Clara Wastewater Treatment Plant) stated emphatically that current regulations do not permit the discharge of **any** chemicals into storm drains. Mike Callahan then noted that the discharge of spent cleaning baths to a POTW may or may not be acceptable, depending on the cleaning chemistry and soils removed. The Panel agreed with his analysis. His recommendations helped develop the Vendor Responsibility criterion regarding disposal.

The Panel expressed the opinion that if a cleaning product were to be discharged directly to the environment, then additional environment testing might be justified. If, however, a cleaning chemistry would be recycled or discharged to a POTW, there would be considerably lower environmental risk and less need for such tests. A biodegradation test seemed to be most relevant for predicting whether the cleaning chemistry would degrade in a waste water treatment plant. Panel members noted that many aqueous and semi-aqueous cleaning chemistries have fairly high aquatic toxicities. However, if they are discharged to a waste water treatment plant, their environmental impact will probably be minimal.

The Panel generally concurred that an "environmental gate" should be included in the criteria, although it was not clear what the particulars of such a gate ought to be. It would probably be a more subjective criterion than many of the others, and would give the Expert Panel considerable leeway in specifying additional requirements. More environmental data from the manufacturer might be necessary before deciding on additional testing.

In summary, the Stakeholder Panel was in general agreement on the following points.

- The Expert Panel should formally address the issue of environmental impacts of cleaning chemistries passing Stage A Criteria. At this point in the certification process, the Expert Panel should have a good idea about product use and disposal.

- The Expert Panel's default option is to not require any additional testing unless specific points of concern arise. If such concern is voiced, the Expert Panel can then request additional information from a manufacturer, or require additional testing if such information is not available.

- The Expert Panel should consider likely use scenarios and potential release pathways for the cleaning chemistry. (For example, a product promoted for use in a field setting, with high probability of direct release to the environment, may require fairly extensive environmental testing. Alternatively, the manufacturer could withdraw its recommendation to use the cleaning chemistry in the field.)

- The Expert Panel should consider a cleaning chemistry's biodegradability and potential for bioaccumulation. Concern may be raised if the chemical's structure is similar to that of a known problematic compound.

- New cleaning chemistries and new chemical compounds should receive particular scrutiny. Breakdown products should be considered.

- The alternative cleaning chemistry criteria should contain reference to specific protocols (such as EPA's or OECD's) to be used if the Expert Panel determines the need to perform aquatic toxicity, bioaccumulation or biodegradability testing.

IV. Preliminary Recommendations For Alternative Cleaning Equipment And Equipment/Chemistry Combination Systems

This protocol contains recommendations for criteria to certify either an alternative cleaning equipment system, or a combination system that includes delivery equipment and a particular cleaning chemistry. The purpose of this certification is to identify cleaning systems whose use will help reduce health and environmental risks associated with industrial cleaning operations, without sacrificing cleaning performance.

Note: The development of these recommendations was begun late in the course of this project. As a result, they are far less developed than those above for cleaning chemistries. LLNL and the Stakeholder Panel view these as **initial** recommendations for the general form of equipment criteria. More work is required before they are complete.

The Stakeholder Panel identified the following guidelines and suggestions for further development of the equipment and equipment/chemistry criteria:

- Distinct methods should be identified for evaluating a piece of equipment versus an equipment/chemistry combination.

- The certification should focus on industrial cleaning rather than consumer cleaning equipment.

- Cleaning equipment impacts on human health and safety should be considered. For example, should equipment intended for use with a toxic chemical be considered for certification? While it may be safe to use such equipment when it is new or well maintained, improper installation or operation, or lack of maintenance may render the equipment dangerous. Mike Beeks (Brulin Corporation) reiterated that the aim of this project it to reduce human and environmental risk. Use of proper equipment with toxic chemicals can do that, and it may be appropriate to certify the best and most effective equipment options.

- Even equipment that uses no chemicals, such as steam cleaning, should be examined for its potential health impacts.

- Certification of cleaning equipment/chemistries does not indicate that they are completely safe.

- Both the quality and quantity of waste generated by the cleaning system should be considered.

- In general, equipment that releases chemicals directly to the environment should not be certified.

- Issues such as containment, energy requirements, and mechanical hazards (pinching, falling, fire, explosion, etc.) should be addressed in the criteria.

- John Butenhoff (3M) pointed out that organizations such as Underwriters' Laboratory, OSHA and NFPA also play a part in evaluating equipment safety. It is important not to duplicate their efforts.

- Dennis Zupan (Brulin Corporation) mentioned to the Panel that equipment can appear satisfactory in an engineering drawing and specifications, but still have a number of application problems. He suggested that several equipment manufacturers be involved to provide further insight.

- For a given piece of equipment, use of the correct chemistry is important. Kathleen Wolf (IRTA) gave the example that terpene used in a spray cabinet could create an explosion hazard. Equipment certification should require inclusion of explicit instructions in the vendor literature regarding appropriate chemistries.

- An Expert Panel is needed to evaluate applications for certification. This Expert Panel would need to have different skill sets, however, than for evaluating alternative chemistries.

- The Expert Panel may want to develop a matrix matching cleaning chemistries with appropriate equipment and applications.

- Vendor services such as recycling or disposal, when part of the cleaning system being evaluated, should be studied as well.

- The certification process should help to ensure that the vendor's marketing literature is not deceptive or ambiguous, and that claims are accurate.

- The Expert Panel should define the terms "adequate controls" and "accepted engineering practices."

Certification Classes

Candidate cleaning equipment will be subjected to a two-stage evaluation procedure, to determine appropriate certification. Cleaning equipment may receive one or more of the following classes of certification:

- **Precision metals cleaning:** For parts produced in close tolerance electroplating, machining, casting, and other types of metal fabrication operations.

- **Precision electronics cleaning:** Includes printed circuit board, semiconductor, and electronic component cleaning operations.

- **General purpose cleaning:** For less demanding applications such as automobile repair shop cleaning.

Filing Fees

An Applicant will pay an initial fee (to be determined) for the candidate system to be examined, and for appropriate tests to be formulated to determine compliance with manufacturer's claims and the criteria described below. The Applicant will be informed of the costs of the required tests Upon payment, the Applicant's equipment will be evaluated.

Manufacturers' Claims and Identification of Comparable Equipment

The Applicant must supply DTSC with all performance and environmental claims it is making, and include constraints, limitations, and operating parameters for the technology. The Applicant must also supply information on the cleaning chemistries suggested for use with the equipment.

The Applicant must identify existing cleaning equipment chemistries that process parts similar to the system under examination, that can serve as reference points for the certification analysis. (For instance, if the Applicant seeks certification for a new spray cleaning system, it should supply information on traditional spray cleaning equipment that can be used as benchmarks in the analysis.) The system being certified should provide reductions in health or environmental risks that traditional systems do not provide, without sacrificing cleaning performance.

The Expert Panel

The Expert Panel will be composed of individuals with the background and experience to evaluate cleaning equipment and equipment/chemistry combinations. The appropriate composition of this Expert Panel is probably significantly different than the one for evaluating cleaning chemistries. The Expert Panel for evaluating equipment may include manufacturers, designers, and users of cleaning equipment, as well environmental scientists and engineers, industrial hygienists, toxicologists, and other specialists.

V. Certification Protocols

1.0 Performance Verification

Criterion recommendation: *Manufacturers pursuing certification of their cleaning chemistries must provide the names, addresses and phone numbers of, and points of contact in at least ten shops currently using the equipment, and satisfied with its performance. Applicants should select a group of facilities covering a wide spectrum of shop sizes, various numbers of employees, and different cleaning methods. It is advisable that large and small businesses be included, as well as both manual and automated cleaning operations.*

Note: All proprietary product information supplied by the Applicant, and labeled as such, will be treated in strict confidence.

When contacted by the Expert Panel, the shop contact persons will be asked to provide information on the operations in which the equipment is being used (i.e. what is cleaned, how the equipment is used, how cleanliness is measured, what level of cleanliness is to be attained, and environmental and health hazards associated with the equipment).

Besides verifying that the candidate system can be successfully used, this information will identify the particular types of applications (precision electronics cleaning, precision metal parts cleaning, or general purpose cleaning) for which the system is suitable. Of the ten or more shops supplied, the Applicant should supply information on at least three shops using the system in each application for which certification is desired. (For instance, if certification of the system for a precision metal parts cleaning is desired, then at least three shops using the system in this way should be provided).

2.0 Test Procedure Development

Criterion recommendation: *Starting with the manufacturer's equipment performance claims and knowledge of similar equipment against which the new technology can be benchmarked, the Expert Panel will formulate a detailed set of test procedures to determine the specific certification appropriate for the equipment or system. The cost of conducting these tests and the environmental impact analysis will also be determined.*

If the manufacturer is selling a cleaning system package that includes both a cleaning chemistry and a specific piece of application equipment to be used with that cleaning chemistry, the test procedure must take this into account, and examine the efficacy of the equipment/cleaning chemistry system.

3.0 Verification of Manufacturer's Claims and Performance of Benchmarking Tests

Criterion recommendation: *In conducting this analysis, care will be given to the following issues.*

- *Equipment should be constructed in a reliable manner exhibiting sound engineering principles.*
- *Capabilities for adequate control and monitoring of operating conditions should be included.*

Verification of a manufacturer's claims will typically be accomplished using a combination of bench testing of the new technology at the manufacturer's facilities, inspection of operational data, and comparison with similar technologies on the market. End users of both the new and traditional technologies will be interviewed.

4.0 Environmental and Health Risk Analysis

Criterion recommendation: *The candidate system must exhibit a significant reduction in environmental or health risks when compared with traditional technologies. Containment capabilities of the equipment must be adequate to protect workers and the environment from chemical releases. Potential impacts on air, water, and soil, will be evaluated. Special attention will be given to atmospheric risks such as potential releases of precursor organic compounds, as well as the potential for releases of problematic substances to ground water or surface water bodies or to POTWs. For instance, a spray cleaning system will be closely scrutinized for pathways by which problematic chemicals could enter the atmosphere; and a manufacturer's methods to prevent such occurrences will be studied.*

5.0 Vendor Responsibility Verification

Criterion recommendation: *Vendor instructions must include clear directions on the proper, safe use of the cleaning system and appropriate operating and maintenance procedures.*

Vendor literature must include information on the possible hazards of the equipment, and how to minimize them, as well as appropriate personal protective equipment for users. The vendor must also provide instructions for proper recycling or disposal of wastes generated during normal use of the system. Vendors are strongly encouraged to:

- *conduct short seminars for users on the safe, proper way to employ its equipment; and*
- *develop a closed loop recycling option for wastes generated during normal use of the system. Vendors should accept some responsibility for proper equipment use, and for waste disposal. For instance, a "total service concept" could be offered by the vendor, in which spent cleaning chemicals are collected and reconstituted or processed for disposal by the vendor. (Note: The vendor must have the proper hazardous waste permits in order to offer such an off-site recycling option to the user shops.)*

VI. Appeals Procedure Recommendations

The appeals procedure gives Applicants a route to address aspects of the criteria for which they feel their product needs special consideration, or to challenge the criteria process when their product does not pass. An appeal should contain the following:

- Identification of the criteria for which the Applicant feels an exception should be made; and
- Presentation of substantial evidence supporting that exception.

The Expert Panel will hear appeals. Grounds for considering an exception to the criteria include the following situations.

- **The criterion disqualifying the cleaning chemistry or cleaning system does not apply to the situation.**

- **A unique application exists, for which no other cleaning technology performs adequately while offering lower environmental and human health risks.** In this case, the technology would be certified only for the unique application.

- **The cleaning chemistry is supplied along with application equipment that provides a reduced-risk, "controlled environment."** Certain solvents can be used with equipment that reduces emissions and worker exposure, and the company's recycling policies limit releases to the environment. Any certification for such a system would be granted only for the chemistry/equipment combination, not for the chemistry by itself.

VII. Periodic Review Requirements

All certified cleaning chemistries must undergo a re-examination every five years, for the purpose of reapproving the technology. Recertification analysis is conducted in considerably less detail than the original analysis. Recertification analysis would establish that the original estimates of human or environmental health risks and the efficient performance of the cleaning chemistry remain substantially unchanged. Any evidence of degradation to human or environmental health, or reduced performance would require retesting and recertification.

If changes are made to the chemical composition of a cleaning chemistry, the manufacturer must notify DTSC immediately (or as soon as it becomes aware of the changes). Modifications to a product's chemistry may be intentional, to enhance its properties, or may result from a change of raw materials suppliers. Modifications can also result when a supplier buys its chemicals from a new source that may introduce different impurities into them. DTSC will analyze the changes to the cleaning chemistries and determine whether a recertification process is necessary.

TABLES

APPENDICES

Appendix I **Total Equivalent Warming Impact (TEWI)**
Source: 3M Company

Appendix II **Clean Air Solvent Certification Protocol**
Source: South Coast Air Quality Management District *Clean Air Solvent Certification Protocol*, Appendix I, "SCAQMD Method 313"

Appendix III **Alternative Cleaning Chemistry Criteria ("Revision XX")**
Source: Mike Callahan, Jacobs Engineering, Inc.